Fatty Acid Dimers and Trimer - Comments of Environmental Defense

(Submitted via Internet 7/10/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Fatty Acid Dimers and Trimer.

The test plan and robust summaries for the fatty acid dimers and trimer were prepared by the Pine Chemicals Association (PCA). This is a well-organized document and it is responsive to the intent of the HPV Challenge Program. The test plan covers 4 CAS numbers: C18 unsaturated dimers, C18 unsaturated trimers, C18 hydrogenated dimers, and crude dimers. All of these substances are complex mixtures. The PCA has previously prepared a test plan for related substances; the current plan addresses tall oil C18 fatty acids, the monomer of the dimers and trimers. The dimers and trimers are prepared by reacting the monomer with a catalyst at 200 degrees. The resulting dimers and trimers are used in adhesive products.

We support establishment of a category for the fatty acid dimers and trimers. They are structurally similar complex mixtures comprised of varying amounts of the same constituents. Fatty acid dimer was appropriately selected as the representative prototype for this category. It is comprised of a number of structures including acrylic dimer, cyclic dimer, aromatic dimer and polycyclic dimer. The test plan did not provide data on the concentration ranges of these substances in preparations used in commerce. Although we realize that these are complex mixtures and the contents are somewhat variable, there certainly must be guidelines for acceptable percentages of the various constituents for quality control. These kinds of data are essential for a rational toxicological evaluation including the use of the data from a given sample to extrapolate to related mixtures.

Available data indicate that the fatty acid dimers and trimer possess low toxicity and are not mutagenic, and adequate data are available to address HPV endpoints with the exception of reproductive and developmental toxicity. Although the sponsors propose to conduct a developmental toxicity study, they contend that a reproductive study is not necessary because the repeat dose study did not indicate histological changes in reproductive organs. However, we recommend that a combined reproductive/developmental study be conducted on fatty acid dimer because of 1) the variable composition of the mixtures, 2) the inability of the repeat dose study to establish a NOEL and 3) the proposed extension of the fatty acid dimer data to address toxicity endpoints for the other members of this category. Moreover, we believe that data from a single representative member of a proposed category needs to be complete for rational and public-health protective extrapolations to data-poor members of that category.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Karen Florini
Senior Attorney, Environmental Defense